NAVAL POSTGRADUATE SCHOOL
Monterey, California

THESIS

INFORMATION MANAGEMENT AND THE BIOLOGICAL WARFARE THREAT

by

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March 2002

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REPORT DOCUMENTATION PAGE			Form Approved OMB No. 0704-0188
Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instruction, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Washington headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302, and to the Office of Management and Budget, Paperwork Reduction Project (0704-0188) Washington DC 20503.			
1. AGENCY USE ONLY *(Leave blank)*	**2. REPORT DATE** March 2002	**3. REPORT TYPE AND DATES COVERED** Master's Thesis	
4. TITLE AND SUBTITLE: Information Management and the Biological Warfare Threat			**5. FUNDING NUMBERS**
6. AUTHOR(S) Martinez, Antonio II			
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Naval Postgraduate School Monterey, CA 93943-5000			**8. PERFORMING ORGANIZATION REPORT NUMBER**
9. SPONSORING /MONITORING AGENCY NAME(S) AND ADDRESS(ES) N/A			**10. SPONSORING/MONITORING AGENCY REPORT NUMBER**
11. SUPPLEMENTARY NOTES The views expressed in this thesis are those of the author and do not reflect the official policy or position of the Department of Defense or the U.S. Government.			
12a. DISTRIBUTION / AVAILABILITY STATEMENT Approved for public release; distribution is unlimited			**12b. DISTRIBUTION CODE** A

13. ABSTRACT ***(maximum 200 words)***

This thesis explores the implications of information management of government-funded projects on national security objectives. A case study of the Human Genome Project is used to illustrate the risk of information transfer between government sources and private industry and the implications posed to the proliferation of Weapons of Mass Destruction. The issue of risk in information management is approached by developing three theoretical paradigms: the scientific paradigm, the business paradigm and the security paradigm. The findings of this thesis demonstrate an information sharing paradigm favoring full and open access to scientific data currently being practiced by the U.S. Human Genome Project.

The information gathered was acquired via open source information pertaining to the Human Genome Project and related initiatives. The purpose of this thesis was to raise awareness of the dangers in distributing information, funded and supplied by the United States. In addition, recommendations were made to increase the involvement of medical professionals and scientists in the non-proliferation efforts the U.S. is currently involved in.

14. SUBJECT TERMS Human Genome Project, Biological Warfare, Information Management			**15. NUMBER OF PAGES** 83
			16. PRICE CODE
17. SECURITY CLASSIFICATION OF REPORT Unclassified	**18. SECURITY CLASSIFICATION OF THIS PAGE** Unclassified	**19. SECURITY CLASSIFICATION OF ABSTRACT** Unclassified	**20. LIMITATION OF ABSTRACT** UL

NSN 7540-01-280-5500 Standard Form 298 (Rev. 2-89)
Prescribed by ANSI Std. 239-18

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INFORMATION MANAGEMENT AND THE BIOLOGICAL WARFARE THREAT

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Submitted in partial fulfillment of the
requirements for the degree of

MASTER OF SCIENCE IN INFORMATION SYSTEMS AND OPERATIONS

from the

NAVAL POSTGRADAUTE SCHOOL
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ABSTRACT

This thesis explores the implications of information management of government-funded projects on national security objectives. A case study of the Human Genome Project is used to illustrate the risk of information transfer between government sources and private industry and the implications posed to the proliferation of Weapons of Mass Destruction. The issue of risk in information management is approached by developing three theoretical paradigms: the scientific paradigm, the business paradigm and the security paradigm. The findings of this thesis demonstrate an information sharing paradigm favoring full and open access to scientific data currently being practiced by the U.S. Human Genome Project.

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LIST OF ABBREVIATIONS

AG	Australia Group
BW	Biological Warfare
BWC	Biological and Toxin Weapon Convention
CBW	Chemical and Biological Warfare
CIA	Central Intelligence Agency
DOE	Department of Energy
DNA	Deoxyribonucleic acid
ELSI	Ethical, Legal and Social Implications
EPA	Environmental Protection Agency
FBI	Federal Bureau of Investigation
HGP	Human Genome Project
GTL	Genomes to Life
MCP	Microbial Cell Project
MGP	Microbial Genome Project
NCBI	National Center for Biotechnology Information
NIH	National Institute of Health
NHGRI	National Human Genome Research Institute
QDR	Quadrennial Defense Review

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ACKNOWLEDGMENTS

The author wants to thank Prof. Arquilla and Commander Jones for their guidance and patience during the work in performing this investigation. The author would also like to thank Colonel Thomas Moore for setting him on the initial course of this thesis.

I. INTRODUCTION

A. BACKGROUND OF THE BIOLOGICAL THREAT

The effectiveness of biological agents is a difficult topic to measure in military affairs. Biological Warfare has been a part of human conflict for centuries. Throughout history biological agents have been utilized on a tactical level to decimate resistance to military actions. Some examples range from such primitive methods as hurling dead bodies infected with plague over castle walls during sieges, and contaminating water supplies with dead animals, to more sophisticated methods such as dropping plague infected fleas over civilian populations or mailing anthrax-filled letters to specifically targeted leaders. Biological agents as strategic weaponry have only been contemplated seriously over the past several decades, mainly in a capacity to deter aggressors or to fulfill terrorist aims.

Until recently, the delivery and types of biological agents have been relatively restricted. In the "pre-biotechnology revolution" era (pre-twentieth century) biological warfare was rudimentary; armies utilized what agents were naturally available to them. The successful employment of a biological weapon entailed as much risk to the attacker (with the exception of previous immunity) as to the defender and with little understanding of the true nature of the organism utilized. Today, biotechnology has allowed scientists to handle and manipulate agents reliably, as well as to develop stabilizing techniques for conventional military employment, thus reducing risk of accidental exposure while increasing the success of dissemination techniques. Nations such as Canada, France, Germany, Japan, the Soviet Union and the United Kingdom began to experiment with biological warfare (as a strategic weapon) in the early twentieth century.[1]

[1] Judith Miller, Stephen Engleberg and William Broad, GERMS: Biological weapons and Americas Secret War (New York:Simon & Schuster, 2001) 38.

1. Historical Effectiveness of Biological Warfare

Evidence of the effects of biological warfare on militaries and society as a whole throughout history is a long and sad tale. Until World War II, more victims of war died of war-borne microbes than of battle wounds. The winners of past wars were not always the armies with the best generals and weapons, but were often merely those bearing the nastiest germs to transmit to their enemy. Perhaps the greatest example of this is the Spanish conquest of the New World, the introduction of smallpox decimated Aztec and Inca resistance[2]. Biological warfare conducted during World War II reveals events such as an outbreak of tularemia in Stalingrad in 1942 resulted in one hundred thousand cases targeted at German panzer troops[3]. This alarming rate of tularemia was a ten fold increase in natural cases for the region and was claimed to be a significant role in halting the German armies advance into Russia. In addition, thousands of Chinese civilians were killed by the Japanese Unit 731 in biological attacks using anthrax, typhoid, and plague.

2. Biological Threat in the Twentieth Century

The proliferation of dual use technologies is a complicated issue that I have chosen to address in this thesis. There have been studies connecting current trends in biotechnology with the current biological threat[4]. This thesis is not intended to duplicate these works, but rather to illustrate the consequences of sharing information pertaining to biotechnology in an open forum, such as the internet, with little to no controls in place to monitor the use of that information. The current biotechnology revolution poses a significant threat to today's security environment. The use of biotechnology is difficult to monitor with any degree of specificity and products resulting from genetic manipulation may be nearly impossible to trace. Potential actors that would be capable of threatening the U.S. with BW agents reads as a "who's who" list of nations that have displayed antagonism towards the U.S. (Iraq, North Korea, China, Russia, and Iran).

---

[2] Jared Diamond, Guns, Germs, and Steel: The Fates of Human Societies (New York: Norton, 1999) 197-211

[3] Ken Alibek, Biohazard (New York: Dell, 1999) 30.

[4] British Medical Association, Biotechnology Weapons and Humanity (Amsterdam: Hardwood Academic, 1999)

However, it is the list of terrorist organizations seeking BW capabilities that concerns U.S. security professionals today[5].

3. U.S. Involvement

The history of U.S. involvement with biological agents (as a concerted institutional effort) has been relatively short. The first diplomatic attempt at limiting biological warfare was the 1925 Geneva Protocol for the Prohibiting of the Use in War of Asphyxiating, Poisonous or Other Gases and of Bacteriological Methods of Warfare. This treaty prohibited the use of biological weapons. [Ref. 1] U.S. involvement in biological weapons development began in 1943 at Camp Detrick and rapidly expanded through World War II and into the Cold War. Officially disbanded in 1969 by President Nixon the U.S. biological warfare unit had competed with the Soviet Union for supremacy in an arms race that produced some of the most deadly organisms known to humanity. In an effort to reduce the threat posed by biological warfare the U.S. played an integral role in ratifying the 1972 Biological and Toxin Weapons Convention that prohibited the possession of deadly biological agents except for defensive research[6]. While the Biological Weapons Convention prohibits possession of deadly biological agents it has not effectively addressed the regulatory methods of controlling the technology that could potentially make biological agents such a terrible weapon.

B. THE THREAT POSED BY BIOLOGICAL WEAPONS IN TODAY'S SECURITY ENVIRONMENT

The recent anthrax attacks in the Unites States have served to address the problem biological agents pose to the security of our nation and raise public awareness. This wave of attacks has been the rallying call for many biological warfare specialists who have cautioned governments on the danger posed by biological agents. In the words of Joshua Lederberg "Individuals can make war with these new weapons."[Ref. 2] Even though the perpetrator has yet to be apprehended these attacks serve as a model for future

[5] The Worldwide Biological Warfare Weapons Threat, (Washington, D.C.: Government Printing Office, 2001) 14.

terrorist employment strategies for biological agents. The longer it takes the U.S. to prosecute the responsible member(s) the more relevant these attacks will become in the future. Aum Shinrikyo's attempts at deploying anthrax in Japan and the Rajneeshees deployment of salmonella in Oregon are just a taste of what organizations are willing to embark upon for a cause.

The effectiveness of biological agents in warfare have been touted throughout the world as being a more capable and less expensive[7] alternative than nuclear or chemical weapons. Table 1 illustrates this comparison.

Weapon System	Effect (number of deaths)
1.0 Mt. hydrogen bomb	570,000-1,900,000
1,000 kg Sarin nerve gas	
(a) Clear, sunny day, light breeze	300-700
(b) Overcast day or night, moderate wind	400-800
(c) Clear, calm night	3,000-8,000
100 kg anthrax spores	
(a) Clear, sunny day, light breeze	130,000-460,000
(b) Overcast day or night, moderate wind	420,000-1,400,000
(c) Clear, calm night	1,000,000-3,000,000

Table 1. The Effects of Attacks with Weapons of Mass Destruction. After Ref. [3].

However, a paradox exists within the medical and scientific communities on the development of these weapons of mass destruction. Prior to, during and after World War I, nations embarked on biological weapons programs basically out of fear of other nations[8]. This competition to support the defense of one's nation was a powerful impetus for expansion of scientific research in the field of offensive biological warfare. As an illustration of this impetus felt by "legitimate" scientists conducting research with a

[6]Judith Miller, Stephen Engleberg and William Broad, GERMS: Biological weapons and Americas Secret War (New York:Simon & Schuster, 2001) 69.

[7] In 1969 U.N. experts estimated that the cost of producing mass casualties per square kilometer were as follows: biological-$1 per square kilometer; chemical (nerve agent)-$600 per square kilometer; nuclear-$800 per square kilometer. Richard Danzig, "Biological Warfare a Nation at Risk—a Time to Act." The Strategic Forum 58 (1996).

[8] Judith Miller, Stephen Engleberg and William Broad, GERMS: Biological weapons and Americas Secret War (New York: Simon & Schuster, 2001) 38-65.

purpose of developing a weapon of mass destruction the following excerpt were taken by two Cold War scientists, one Soviet the other American:

> …I liked the work. I discovered an affinity for the meticulous processes involved in culturing organisms. The challenge of manipulating the tiny worlds that appeared under my microscope engaged me more intensely than anything I had ever done before…I knew that the results of my studies could be used to kill people, but I couldn't figure out how to reconcile this knowledge with the pleasure I derived from research.
>
> [Ref. 4]

> At the time we were doing this, the objective was to solve the problem and not consider the philosophical ramification of what we were doing. [Ref. 5]

This illustration of the justification processes scientists go through is a very useful tool. The excerpts point out that justification for a scientist is based on a perception of a threat. It is the motives scientists maintain that may be the true threat with regard to the proliferation of biological warfare techniques.

1. U.S. Quadrennial Defense Review Threat Analysis

The 2001 Quadrennial Defense Review states the following about the current biological threat:

> *Increasing proliferation of CBRNE weapons and ballistic missiles.*
>
> The pervasiveness of proliferation in an era of globalization has increased the availability of technologies and expertise needed to create the military means to challenge directly the United States and its allies and friends. This includes the spread of CBRNE[9] weapons and their means of delivery, as well as advanced conventional weapons. In particular, the pace and scale of recent ballistic missile proliferation has exceeded earlier intelligence estimates and suggests these challenges may grow at a faster pace than previously expected. Likewise, the biotechnology revolution holds the probability of increasing threats of biological warfare.

[9] CBRNE is Chemical, Biological, Radiological, Nuclear and Energy.

And further states:

> *Increasing potential for miscalculation and surprise.*
>
> Together, these military-technical trends create an increased potential for miscalculation and surprise. In recent years, the United States has been surprised by the speed with which other states have progressed in developing weapons of mass destruction and ballistic missiles. In the future, it is unlikely that the United States will be able accurately to predict how successfully other states will exploit the revolution in military affairs, how rapidly potential or actual adversaries will acquire CBRNE weapons and ballistic missiles, or how competitions in space and cyber space will develop.[Ref. 6]

From the QDR we can begin to see the growing concern for the strategic/tactical reach that biological agents possess. Addressing the strategic level, the coupling of biological agents to missile technology could be misleading given the examples of recent anthrax attacks in the U.S. The QDR's recognition of America's susceptibility to being surprised by military-technical trends is a revelation that a "hiders/finders" concept of biological warfare capabilities could lead to significant security threats in the future. Biotechnology is providing the conduit for the proliferation of a knowledge base from which biological warfare agents can be generated.

2. Improved Security Environment for Bio-weapons

The equipment, techniques and education required to conduct offensive biological research and development have never been more easily accessible than today. The internet abounds with information that could be utilized by terrorists (state sponsored or non-state sponsored) to initiate a program. Most techniques and procedures for manipulating microorganisms are taught in universities around the globe. In addition, the U.S. government Freedom of Information Act is another tool that actors could utilize to obtain information about offensive biological warfare.

C. THE OFFENSE-DEFENSE BALANCE AND BIOLOGICAL WEAPONS

Utilizing an offense-defense model to characterize the implications of biological weapons is a useful tool in examining the threat posed by the proliferation of technologies capable of creating these weapons. In an offense-defense model, biological agents might be recognized as an improvement in firepower and would thus logically favor the defensive[10] [Ref. 7]. Biological agents have been a controversial weapon of mass destruction. As a weapon, biological agents require conditions to be met to acquire optimal dispersal for maximum efficacy. In addition, contagious agents pose a special problem of spreading epidemics to unintended targets. However, biological agents offer two characteristics that lead to its appeal in the current security environment: stealth and effectiveness. Historically most engagements that have involved biological agents, agents were utilized in an offensive capacity. This offensive capacity through history was eloquently detailed in *Germs* as:

> …the importance of scientific breakthroughs in the history of war: the dramatic results when offensive capabilities had outstripped defensive measures. The introduction of iron weapons, for instance, had made bronze weapons ineffective. Gunpowder had made the defensive armor of medieval knights obsolete. Horses and cavalries had enabled Asians to sweep through Europe. And now the offensive capability of germs as bioweapons seemed to be outstripping defenses against them. Germs …were "strategic" weapons that could strike deep into the nation's heartland. Such attacks could be attempted by states, terrorist groups they supported or lone actors. "Individuals can make war with these new weapons". To counter such attacks, antiviral drugs and therapeutics were needed. So were new vaccines based on new technologies. [Ref. 8]

The implications of biotechnology and warfare would thus lead one to believe that the offensive nature of biological weapons would far outweigh the defensive nature of medical treatment. Medical treatments are only useful against known agents and are completely reactionary to developing conditions. Current technological developments do not allow for a more proactive defense against biological weapons; however the biotechnology revolution is trying to change this view.

[10] See Keir A. Lieber, "Grasping the Technological Peace," International Security 25 (2000) 71-104.

1. The Threat of Biotechnology

The ability to alter the genetic make-up of an organism (human, plant, microorganism, or virus) poses a significant responsibility on the scientific and medical communities. The proliferation of biotechnology and the implications it poses for societies around the world is forcing national and international organizations to develop governance structures to regulate the biotechnology industry[11]. The implication of the duality of biotechnology is a danger that threatens societies around the world. Biotechnology has produced "miracle" drugs that fend off diseases such as diabetes, vaccines that have controlled disease such as small pox and promises to radically improve our ability to alter the genetic make-up of a human being to combat genetic disorders. In contrast, biotechnology can also be used to improve organisms that are harmful to humans. Producing organisms that could be utilized in a biological warfare capacity is difficult to detect and can be easily mistaken for defensive research.

Revelations from the former Soviet Union on the extent of its biological weapons program have alarmed the world. In his book *Biohazard*, Ken Alibek, a former Soviet scientist from Biopreparat[12], details many projects in the Soviet Unions biological warfare program that used genetic engineering to enhance the performance of biological agent such as anthrax, small pox, marburg, and tularemia. In his revelations Alibek tells us that the Soviet Union placed an emphasis on utilizing advances in biotechnology in making biological agents immune to vaccines, antibiotics, and making the agents more stable in the environment.

2. Cause for Offensive Dominance

Biotechnology is not symmetric when one talks about offensive and defensive biological warfare. With regards for biological warfare, biotechnology favors the creation of biological agents over the creation of defenses against those agents (offense over defense). The reason for this is related to the complexity of the two biological

[11] Francis Fukuyama, "How to Regulate Science," Public Interest 146 (2002): 3-22.

[12] Biopreparat was a civilian branch of the Soviet Unions clandestine, offensive biological warfare program.

systems involved; the biological agents and the human subjects. The main hindrance to bio-defense measures is that all of the current countermeasures involve a more complex biological system: the human body. Current science and technology allow for a greater range of research among less complex biological system such as bacteria, fungi, rickettsiae and viruses. In contrast, research on humans is highly controversial and often requires months and or years of debate, research and development. In addition, biological warfare offers several advantages to an offensive use: stealth of delivery, inexpensive to produce, potential for selectivity and minimum infrastructure required for production.

3. Countermeasures to Biotechnology Threat

The U.S. perception[13] of an imbalance in the offense-defense model has lead to policy initiatives to bring the perceived imbalance into equilibrium. The Biological and Toxin Weapons Convention is one avenue that the U.S. has tried to impress on the current security environment. Another measure taken by the U.S. was an initiative to study and map genomes of various organisms. This initiative is an effort to better understand the processes by which biological systems interact. By studying microbial genomes, scientists hope to obtain genetic signatures for identification of pathogenic organisms and potentially lead to improved vaccines and antibiotics that would assist medical personnel in defending against a biological warfare event as well as an epidemiological event. Studying the human genome has implications for many aspects of preventive medical measures, including disease prevention and immune enhancement. These initiatives by the United States have led the world in biotechnology innovation and scientific discovery. The United States has staked its claim as a pioneer in biotechnology for the sake of humanity (medical role) but risks the potential of late modernizers to surpass its technological superiority and strike out ahead on their own.

[13] Judith Miller, Stephen Engleberg and William Broad, GERMS: Biological weapons and Americas Secret War (New York:Simon & Schuster, 2001) 61-69.

D. IMPETUS FOR THESIS

Upon examination of an offense-defense model of biotechnology in warfare and given the historical impact biological warfare has had on societies a review of current biotechnology governance practices is a must. The sharing of information pertaining to biotechnology in an open forum, such as the internet is one facet of the governance problem that I have chosen to examine. Scientific contributions to warfare have shaped societies and will continue to be a delicate balancing act for nations. After all, as Harvard Professor Matthew Meselson has stated,

> Every major technology—metallurgy, explosives, internal combustion, aviation, electronics, nuclear energy has been intensively exploited, not only for peaceful purposes but also for hostile ones……Unlike the technologies of conventional or even nuclear weapons, biotechnology has the potential to place mass destructive capability in a multitude of hands and, in coming decades, to reach deeply into what we are and how we regard ourselves. [Ref. 9]

The issue at hand is to examine levels of access to human "omatigence"[14] research for further biological study that does not hinder progress or give away methods for unintended use. An evaluation of information management strategies is the purpose of this thesis, to examine preventive measures for disclosing sensitive technologies and knowledge to potential adversaries. I will seek to explore the current research being conducted and/or funded by the Human Genome Project and its related Projects in order to identify areas of information sharing/dissemination that create a potential for the generation/improvement of biological warfare agents.

My choice for utilizing the Human Genome Project results from the concern among many security professionals[15] about releasing too much scientific information into an environment where no controls are placed on who is reviewing potentially sensitive materials. The Human Genome Project is also a good case to examine the pressures involved in management of a project that lead to critical decision-making in one of three areas: scientific progress, business marketing, and national/global security. The Human

[14]Term taken from CDR Shaun Jones meaning "a fusion of omics and informatics and intelligence"

Genome Project is a clear case in which all three of these elements (science, business and security) come into the purview of a government-managed program with serious implications for the proliferation of dual-use technology.

E. OVERVIEW OF THE STUDY

The remainder of this thesis will follow the format below:

1. Chapter II, Theoretical Framework

In this chapter I will discuss the tensions between information policies of openness and guardedness and discuss the three paradigms (scientific, business, security) as a developing factor for information sharing paradigms.

2. Chapter III, The Human Genome Project

In this chapter I will discuss the plans and goals of the HGP. I will use the three paradigms developed in chapter 2 to compare the benefits of scientific discoveries to-date and the concerns for biological misuse.

3. Chapter IV, Sensitivity Analysis

In this chapter I will discuss the case study by describing the problem of proliferating "dual use" technology. I will compare actual events and benefits that have come from the program to potential pitfalls in proliferation. Also, I will discuss the issue of self-promotion in relation to scientific discovery and the implications to societies.

4. Chapter V, Policy Implications

In this chapter I will make recommendations to improve the release of information regarding sensitive technologies and provide concluding remarks on the difficulty of regulating dual use technologies.

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[15] Steve Sternberg, "Could Decoded DNA Information Help Bioterrorists?," USA Today 14 Nov. 2001: 9D

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II. THEORETICAL FRAMEWORK

A. PARADIGMS LOST

In order to evaluate the utility of sharing information pertaining to biotechnology in an open forum, I will propose a theoretical model. This model will aim to demonstrate the forces that have lead to the current information sharing practices of the Human Genome Project. Ultimately the model will seek to become an objective process to judge the benefits of information sharing versus the costs associated with the use of that information for an unintended or unethical purpose as a result of sharing. One must also establish the purpose for the establishment of an information-sharing framework and then examine the consequences that arise from this information framework. This thesis examines the framework of information sharing through the "lens" of three paradigms that have played an integral role in developing the purpose for this framework of information sharing in the Human Genome Project. A paradigm is defined in Webster's Dictionary as: *a philosophical and theoretical framework of a scientific school or discipline within which theories, laws, and generalization and the experiments performed in support of them are formulated.* For the purposes of this thesis the "scientific discipline" refers to information science.

The Human Genome Project is a very unique case study in that it is a government managed project that manages and cooperates with scientific laboratories worldwide that ultimately support a global industry (biotechnology). The purpose of the HGP is to better understand the biological processes of the human body (and other organisms) for the purpose of advancing medical procedures that would save and possibly extend life. This purpose reveals a program steeped in scientific research. The quest for answers posed by science continues to push the boundaries of how we understand who we are and what is our relationship with the environment that surrounds us. In addition, the result of this scientific research leads to the development of products that benefit all of mankind. In a free market world where globalization defines a nation's economic and political affairs, competition for product development becomes a powerful impetus for innovation and becomes a driving factor to carry on the quest for better products.

Of the three paradigms examined in this thesis two are self evident from the defined purpose stated previously. The scientific information-sharing paradigm (quest to better understand the biological process) advocates the free exchange of information for the purpose of increasing the knowledge base by which problems can be solved. The business information-sharing paradigm (advancing medical procedures that would save lives and possibly extend life) advocates a limited sharing of information within a free market environment to enhance competitive practices while avoiding monopolistic practices. The third paradigm examined by this thesis is not as evident in the theme of the Human Genome Project but is a significant concern in today's information age. The security information-sharing paradigm advocates placing limitations on information exchange for the protection of an organization and society as a whole. I discuss each information-sharing paradigm below

1. Scientific Paradigm

The scientific community's free exchange paradigm serves as an outstanding instrument of cooperation in attacking complex problems. One of the most celebrated examples of this paradigm in action is the discovery of the BRCA1 gene in 1994. This gene, found in a mutated form, was linked to an 85 percent chance of developing breast cancer and a 50 percent chance of developing ovarian cancer in women with the defective gene [Ref. 10]. This discovery was assisted by the sharing of information that would lead two competing laboratories to rapidly assimilate the information into techniques that would lead to the ultimate discovery of the BRCA1 gene. The discovery of this gene would lead to the development of medical tests that could detect the defective gene in women who were assessed as being at risk. While the result of the information-sharing did not produce a product that could accurately predict whether a woman would actually develop breast or ovarian cancer it has proven a useful tool in improving the lives of those women who have been identified as having the defective gene by allowing those women to take preventive measures before developing cancer.

2. Business Paradigm

The business information-sharing paradigm serves to keep companies on the edge of development while at the same time limiting competitors from incursions that would eat into profits. This information-sharing paradigm is best illustrated in the fierce competition for gene patenting in the biotechnology industry. In 1992 Agracetus (an American biotechnology company) received a patent for all genetically engineered cotton plants. The patent was for the process of genetically engineering cotton plants. This patent was filed and granted in four cotton-producing countries that lead to a virtual monopoly held by Agracetus in these countries, eliminating the import of new cotton varieties. [Ref. 11] While the result of this information-sharing paradigm seems to clash with the 'fair play' desired by business it is a powerful impetus for competition among corporations to produce a unique product in order to fill a niche in a market for profit.

3. Security Paradigm

The security information-sharing paradigm is perhaps the most controversial in a society that covets the free exchange of ideas and free speech. In April 1998, senior U.S. intelligence officers, including FBI Director Louis Freeh and CIA chief George Tenet, raised an alarm about materials the Environmental Protection Agency planned to post on the internet. The EPA was preparing to make available information about more than 60,000 sites where chemicals are stored and potential worst-case accidents that could happen at the sites. A confidential risk report warned that making the information available to the public would increase seven fold the risk of a terrorist attack. [Ref. 12] While the result of this information-sharing paradigm has implications on the forum in which information is released it requires an intense vigilance to support and maintain over a period of time.

B. SECRET TO SCIENTIFIC INNOVATION

There is no secret to scientific innovation. From the very beginnings of the biotechnology revolution (circa 1944, with the realization that DNA was the molecule responsible for heredity) scientific innovation has taken place as an evolutionary process

through the 'normal science' of biotechnology. Thomas Kuhn defines normal science as "research firmly based upon one or more past scientific achievements that some particular community acknowledges for a time supplying the foundation for its further practice [Ref. 13]."

In Kuhn's essay *The Structure of Scientific Revolution* he illustrates the development of a scientific field based on an event he calls a scientific revolution. The secret to scientific innovation is best described by utilizing this scientific revolution concept to understand that science as we know it is not as objective as we might be led to believe. Science as we know it is merely a series of paradigms that support a discipline to an end point (a crisis) that requires a revolution (or paradigm shift) of ideas to continue to assist scientists in explaining the world around them. Yet this revolutionary cycle that is required is an extremely competitive period that seeks to persuade various factions within a discipline towards acceptance of a particular paradigm. The quest to understand biological processes led to the development of techniques from many scientific communities to study organisms. This culmination of techniques would lead scientists to a crisis concerning the very substance of life itself.

For the field of biotechnology this scientific revolution was initiated by Johann Miescher and set into motion by Fred Griffith and solidified by Oswald Avery. In 1869 Johann Miescher discovered molecular DNA, in 1928 Fred Griffith revealed that hereditary molecules could be isolated, in 1944 Oswald Avery correlated DNA with hereditary properties. These revelations are the basis for which the normal science of biotechnology (solidified by Avery) is based. It has been the scientific revolution of DNA that has led the science of biotechnology to what it is today.

The establishment of biotechnology as a science is not an exact statement. Biotechnology is a culmination of techniques drawn from various scientific fields that work towards the same goal: to use the properties of living things to make products or provide services [Ref. 14]. This is the junction by which the scientific paradigm and business paradigm interface: products and services. While the science of biotechnology is to continually seek out answers to questions about us and our environment, it is intimately linked to the business of biotechnology. If science produced information that

did not serve a useful purpose, would that science prove useful and thus continue as an endeavor worthy of following?

C. SECRET TO BUSINESS EFFICIENCY

Business practices within the field of biotechnology have experienced a wide range of controversial issues. Issues that call into question ethics, morality, fair business practices and national security. However, in a global economy that favors capitalistic practices, corporations are viewed as the ideal organization for innovation in society. In his book *The Role of Business in Society*, John Diebold discusses the role of corporations:

> Competitive enterprise possesses a dynamism and ability to innovate that bureaucracies divorced from markets do not possess. Despite its faults, the profit-seeking enterprise provides the best mechanism we have for spurring efficiency in resource allocation, for encouraging innovation and application of resource in entirely new modes, and for securing the transference of resources to new product lines. Indeed, the dynamics of the market and feedback control through profit-not corporate form or management techniques-make profit enterprise the most effective innovator and resource allocator we have ever invented. For society to benefit from this much-needed ability to fulfill human needs, it is the social responsibility of business to pursue profit. The task of government is to establish incentives and constraints in such a way that profit is made during what society most needs done, in a manner society finds acceptable. Good corporate citizenship is not enough….the bigger dangers have come when business has cooperated as a "good corporate citizen" with government, and especially when it has cultivated its public relation with either politicians or the intelligentsia-because then sometimes monopoly has been allowed. [Ref. 15]

This view of corporations as a tool for the betterment of society is a good model to consider the ramifications of business decisions in the biotechnology industry. The bottom-line for any corporation in a capitalist environment is profit. John Diebold warns against allowing business' to "do the right thing" of their own accord if social concerns are at stake. Diebold also warns against close cooperation between government and business, claiming that if not left to natural market influences monopolistic regimes could stifle growth and innovation.

In biotechnology there is no more controversial topic than the role of business, especially with regard to gene patenting. The business requirement for the patenting of genes is vital from the perspective of the biotechnology industry. Companies argue that they need the protection of a patent to repay the cost of their research and development. It typically takes several years and millions of dollars to bring a biotechnology application to market. Companies aim to restrict other researchers in the same field, slow progress and divide the industry by seeking patents in broad areas (concepts, a technique, or a group of plants or animals). [Ref. 16] However, the private ownership of genetic materials is a volatile issue in societies around the world. Diebold's warning against trusting business to be a good citizen without outside influence is an issue that has many people concerned for the exploitation of biological processes that could have a detrimental effect on society (all within the legal context of a patent law).

Thus, society's mistrust of business as a 'good citizen' and government's dependence on the innovation inherent in business play an interesting role in the development of an industry. The business of biotechnology has forced societies around the world to involve themselves in debating the issues that have arisen from the science of biotechnology. This involvement can only be useful if held in an open environment where free speech is allowed to develop the policies required to regulate the use of scientific information for profitable purposes that are a reflection of the demands and concerns of a population.

D. NO SECRET TO SECURITY GUARDEDNESS

The security paradigm that I present in this chapter is essentially an abstract form of information operations. Information operations can be a form of national power that use information content and technology as strategic instruments to shape fundamental political, economic, military and cultural forces on a long-term basis to affect the global behavior of governments, supra-governmental organizations and societies. This type of national "information power" can be defined in terms of military and governmental (and private sector) actions to control and exploit the strategic information environment across the conflict spectrum. [Ref. 17]

This kind of information operation could be utilized in an information warfare capacity should information be utilized against members of the international HGP members. Information warfare is defined by Dorothy Denning as:

> ….offensive and defensive operations against information resources of a "win-lose" nature. It is conducted because information resources have value to people. Offensive operations aim to increase this value for the offensive while decreasing it for the defense. Defensive operations seek to counter potential losses of value. [Ref. 18]

To elaborate on the relation between the information sharing paradigm and information warfare utilizing Denning's model, open-source information concerning a dual-use technology has an operational value. This operational value is open-source information pertaining to the HGP is of equal value to actors who intend to use the information for defensive or offensive biological purposes. However, it is the comparative value of the end products as a result of the information shared that most concerns security professionals.

The concept of information as a component of national power requires an environment for information to exist in. This information environment according to Dr. Dan Kuehl of the National Defense University consists of two realms: the physical and the contextual. In the case of an open-source information resource the contextual realm of information is the most relevant. Herein lies the challenge of dual use technologies. As a matter of national security, the science of biotechnology is a grave concern for many scientists and security professionals, yet for the intended purpose of its use it is equally useful. In what follows, I will explore ways of managing this tension.

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III. THE HUMAN GENOME PROJECT

A. THE HUMAN GENOME PROJECT

The HGP was initiated in October 1990 for the purpose of mapping the human genome in order to serve as a stepping-stone for improvements in medical techniques for treating diseases. The mission of the HGP is stated as:

> The U.S. Human Genome Project (HGP), composed of the DOE and NIH Human Genome Programs, is the national coordinated effort to characterize all human genetic material by determining the complete sequence of the DNA in the human genome. The HGP's ultimate goal is to discover all the more than 30,000 human genes and render them accessible for further biological study. An ambitious schedule has been set to complete the full sequence by the end of 2003. The Human Genome Program supports research projects at universities, the DOE Joint Genome Institute, DOE and NIH-owned national laboratories, and other research organizations. As part of the international Human Genome Project, vital and very active genome research is being pursued by researchers and science funding agencies outside the United States. [Ref. 19]

The Office of Biological and Environmental Research (OBER) within the Department of Energy and the National Human Genome Research Institute (NHGRI) within the National Institute of Health handle administration of the program. In 1987 three genome research centers were established at Lawrence Livermore, Los Alamos and Lawrence Berkeley, which were all subsequently merged into the DOE Joint Genome Institute. International efforts have also played a critical role in the project's success, with at least 18 countries now supporting programs for analyzing the genomes of a variety of organisms ranging from microbes to economically important plants and animals to humans.

The HGP has already identified single genes associated with various genetic disorders. The HGP also helped to spawn multiple DOE and NIH follow-on programs to continue the goal of mastering the biological processes that control life as we know it. Perhaps the most significant impact the Human Genome Project has played in the overall mission to map the human genome is the coordination of technology development for

scientific research. The HGP has also played a major role in bringing about an "economy of force" among research facilities and private sector companies through information and program management. The study of life at the most basic level has spurred many debates about the privacy, ethics, and the legality of genetics in society. To study the effects of the HGP, DOE and NIH established an ethical, legal, societal implications research fund.

Projects such as the Microbial Genome Project, Microbial Cell Project, Genomes to Life Project, and the Human Genome Diversity Project were all spin-offs of the HGP that would take the next step in developing a better understanding of how genes interacted inside the nucleus of the cell and what the mechanism for gene expression was.

1. The Microbial Genome Project

The Microbial Genome Program's goal is to completely sequence the genomes of microbes, primarily bacteria. However, unlike the massive human genome, which is taking multiple years to complete, many microbial genomes can be completely sequenced in weeks or months. Through the study and understanding of a diverse group of microbes, solutions are nearer for challenges in environmental cleanup, medicine, agriculture, industrial processes, energy production and use, and biological nonproliferation (understanding and detecting biowarfare agents), to name a few.[Ref. 20] The MGP was initiated in 1994 to sequence the genomes of environmentally and industrially interesting microbes. The U.S. Department of Agriculture, the National Science Foundation and the private sector, in addition to the DOE and NIH, conduct research in this field.

2. The Microbial Cell Project

The purpose of the Microbial Cell Project is to determine and characterize the minimum set of genes and corresponding gene products necessary to sustain a simple free-living microbial cell, express the genes to produce the relevant proteins, and determine their structure [Ref. 21]. The MCP takes a whole-genome approach to understanding the function and regulation of all genes for a single living system and the pathways in which the protein products interact. The MCP's ultimate aim is to learn enough about cellular functions so they can be manipulated knowledgeably to enhance

beneficial and suppress unintended effects [Ref. 22]. The initiation of the MCP was to provide a stepping-stone for the Genomes to Life Project.

3. The Genomes to Life Program

The Genomes to Life (GTL) program will take the logical next step: a quest to understand the composition and function of the biochemical networks and pathways that carry out essential processes of living organisms. [Ref. 23] The GTL program was initiated in 1999. The Office of Biological and Environmental Research and Office of Advanced Scientific Computing Research in the U.S. Department of Energy cooperate on the research in the GTL program. The GTL program focuses on: identifying the protein machines that carry out critical life functions, characterizing the gene regulatory networks that control these machines, exploring the functional repertoire of complex microbial communities in their natural environments to provide a foundation for understanding and using their remarkably diverse capabilities to address DOE missions, and developing the computational capabilities to integrate and understand these data and begin to model complex biological systems. [Ref. 24]

4. The Human Genome Diversity Project

The Human Genome Diversity Project aims to compare the genetic material of scores of remote, isolated native population around the world, in the interests of understanding human history and migration [Ref. 25]. This project would lead to a fundamental understanding on genetic differentiation among humans that will prove critical in identifying genes.

B. PARADIGM INTERACTION

As I have stated previously the HGP is a unique program due to its foundation in publicly funded research and support of an industry. All three of the paradigms discussed in chapter II (scientific, business and security) play an integral role in developing the existing framework for sharing information. However, it is the weight of these three

paradigms as the basis for the current policy towards information sharing that I intend to address in the following chapters.

In his book *Cracking the Genome: Inside the Race to Unlock Human DNA*, Kevin Davies illustrates the interaction of these three paradigms in his telling of the events that lead to the development of the HGP to its present day form. The foundation for the HGP (as previously stated) was based on the need to understand biological processes for the benefit of mankind. This telling story of the development of the HGP as a scientific venture that led to a marriage with commercial industry is an example of a scientific project that lead to an explosion of new technologies and discoveries that lead to a profound impact on an industry and society as a whole. The successes of the HGP are a testament to human innovation and cooperation, however, the knowledge produced and the form that knowledge is released in are a concern of many security professionals as well as of scientists in the field of genetics. The scientists involved in the HGP were aware of the ramifications of their research for good and ill, and the media form that they chose for the release of information is the topic that most concerns this thesis. The sensationalization of discoveries and eagerness to educate a population to a level of understanding for the appreciation of the research drew attention (perhaps unwanted attention) to the possibilities of biotechnology. When confronted with the prospect of biological warriors utilizing their ground-breaking techniques, reaction from the scientific community was one of concern yet confidence in the abilities of their techniques to provide sufficient defenses against biological threats.

1. Scientific-Business Paradigm Interaction

A great deal of the basic knowledge underlying biotechnology was developed using public funding. The scientific information-sharing paradigm coexists with the business paradigm to provide useful services to society. Science produces a technique or product that is marketed by business for profit in a supply and demand economic model. This feedback mechanism of supply and demand translates into a scientific progress report for the effectiveness of research programs. However, within the business and scientific communities there is a tension over intellectual property. Technological

innovations and gene patents required by business create possessiveness about basic information, reducing the relatively free exchange of ideas and data traditional among scientists [Ref. 26].

> Science operates according to a "market" of its own, one that has rules and values different from those of commercial markets. While protection of intellectual property may concern a scientist who is writing a textbook, that same scientist, publishing a paper in a scientific journal, is motivated by the desire to propagate ideas, with the expectation of full and open access to the results. To commercial publishers (including many professional societies), protection of intellectual property means protection of the rights to reproduce and distribute printed material. To scientists, protection of intellectual property usually signifies assurance of proper attribution and credit for ideas and achievements. Generally, scientists are more concerned that their work be read and used rather than that it be protected against unauthorized copying. [Ref. 27]

2. Scientific-Security Paradigm Interaction

The scientific and security paradigms can be viewed as opposing ends of an information-sharing spectrum. During the Clinton administration the Human Genome Project (HGP) was seen as a key element in the United States ability to level the playing field against biological warfare agents. [Ref. 28] However, this hope for bio-defense measures was also tempered by the fear of their use in offensive biological warfare agents. In fact, from a security perspective, defensive biological warfare has become a critical area of concern highlighted by the anthrax attacks in the U.S. following the September 11 terrorist attacks on the World Trade Center.

3. Business-Security Paradigm Interaction

Gene patenting (discussed previously) is utilized by business to protect their investment into a particular scientific innovation. This guardedness towards a product is aimed at creating a niche for business in a particular field by disallowing competition, or at a minimum increasing a competitive advantage in a market. As illustrated in the previous chapter, business exists for the security of a corporation and not for the security

of the population at large. In this respect, business must have boundaries defined for its operation within a national security context.

C. IMPETUS FOR "SCIENTIFIC" INNOVATION

Scientific innovation is the heart of the organization that is the HGP. The very design and purpose of the HGP has been to facilitate scientific innovation in order to reap the benefits of scientific discoveries. By creating an administrative adhocracy organizational structure[16] among several nations the member nations have committed to a project for the betterment of mankind. Yet this noble cause is targeted at a problem so complex that the search for new technologies to accomplish the research required has dominated the project to date. With an estimated 100,000 genes (later revised to 30,000) to discover and study, research to date has concentrated on the technologies to improve research in correlating of genes to a particular function.

Two problems were identified that would have to be addressed to meet the 2005 target date for sequencing the entire human genome: first, construction of a complete physical map[17] of each chromosome and second, improvements in sequencing technology. In order to handle the first problem, the scientific information-sharing paradigm came to the fore. In 1996 all major genome institutes in the public domain committed to The Bermuda Accord (developed at the first International Strategy Meeting on Human Genome Sequencing held in Bermuda). The Bermuda Accord states "All human genome sequence information should be freely available in the public domain in order to encourage research and development to maximize its benefit to society." [Ref. 29] This open forum for information sharing would assist genomic research institutes in coordinating the sequencing of over three billion base pairs of DNA. The second problem was tackled by genomic institutes and later outsourced to the private sector. This outsourcing of technologies would lead to competition, coveted by free market economies, within the biotechnology industry.

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[16] Mintzberg, Henry, "Organization Design: Fashion or Fit?," Harvard Business Review, 59, 112, January-February 1981.

[17] A physical map is a map of the locations of identifiable landmarks on DNA (e.g. restriction enzyme cutting sites, genes), regardless of inheritance. The highest resolution map would be the complete nucleotide sequence of the chromosome.

From the start, HGP planners anticipated and promoted the private sector's participation in developing and commercializing genomic resources and applications. The HGP's successes in establishing an infrastructure and funding high-throughput technology development have given rise to commercially viable products and services, with the private sector now taking on more of the risk. Substantial public-sector research and development investment often is needed in feasibility demonstrations before such start-up ventures as those by Celera Genomics, Incyte, and Human Genome Sciences can begin. In turn, these companies furnish valuable commercial services that the government cannot provide, and the taxes returned by their successes easily repay fundamental public investments[18]. The HGP's commitment from the outset has been to create a scientific standard (an entire reference genome). Most private-sector human genome sequencing projects, however, focus on gathering just enough DNA to meet their customers' needs probably in the 95% to 99% range for gene-rich, potentially lucrative regions. Such private data continue to be enriched greatly by accurate free public mapping (location) and sequence information. [Ref 30]

D. SOME IMPLICATIONS

Science and ethics exist in tension. The bulk of scientific research is after all focused on the "how can we do something" or the "what would happen if we did something." Rarely is the question asked "should we do this?" Recognizing that the struggle to resist one disease or another will always be with us, like death itself, what is the goal of medicine? How does biotechnology help that goal? The overriding approach of biotechnology is to control or fix whatever threatens ill health. It tends to emphasize high-tech intervention and the search for cures. [Ref. 31]

The complete human genetic sequence will reveal the fundamental properties of all human genes, allowing their functions and interactions to be integrated into a miraculously complete picture of human biology and evolution. In the same way as the building blocks of chemistry were uncovered 130 years ago thanks to the work of

[18] The idea of a public good is addressed in John Diebold, The Role of Business in Society (New York: AMACOM, 1982).

Mendeleyev, Newlands, and others, biology too is on the verge of becoming finite[19]. [Ref. 32] This finite future in biology has serious implications for biological warfare in general. From a biological warfare perspective, Steven Block details various properties a scientist might attempt to develop within a pathogen utilizing finite scientific techniques, these include: Safer handling and deployment; Easier propagation and/or distribution; Improved ability to target the host; Greater tansmissivity, infectivity; More difficulty in detection; Greater toxicity, more difficulty in combating; and Self-limiting/Self-enhancing. [Ref. 33]

For medicine the finite future of biology will provide equally beneficial implications by improving detection, diagnosis, and preventive measures. The promises of gene therapy, microbial research, and immunological research cast a promising future for the health care industry. Research directly related to the HGP has already produced detection procedures for several genetic diseases that have improved the lives of countless people. The future not only holds the potential for more detection procedures but also the possibility of correcting genetic deficiencies at the root cause, the DNA inside us.

All of the genome sequence generated by the HGP has been deposited into public databases freely accessible by anyone with a connection to the Internet. Disseminating information in the public domain encourages widespread use of information, minimizes transaction costs, and makes research and development cheaper and faster. Of particular relevance to research science, a vigorous public domain can supply a meeting place for people, information, and ideas that might not find each other in the course of more organized, licensed encounters. Information in the public domain is accessible to users who otherwise would be priced out of the market. [Ref. 34]

Global diffusion of biotechnology is a serious matter for the potential of biological warfare. The U.S. could be seen as a major proliferator of biotechnology in the global market. The book *Bits of Power: Issues in Global Access to Scientific Data* illustrates how the U.S. has accomplished this proliferation status.

[19] Reference to "finite" science is given by Eric Lander: "The Human Genome Project aims to produce biology's periodic table-not 100 elements, but 100,000 genes: not a rectangle reflecting electron valences, but a tree structure, depicting ancestral and functional affinities among the human genes."

> Freedom of inquiry, the full and open availability of scientific data on an international basis, and the open publication of results are cornerstones of basic research that U.S. law and tradition have long upheld. For many decades, the United States has been a leader in the collection and dissemination of scientific data, and in the discovery and creation of new knowledge. By sharing and exchanging data with the international community and by openly publishing the results of research, all countries, including the United States, have benefited. In this century's dramatic growth of scientific knowledge—an expansion motivated by a combination of forces including military, commercial, public benefit (especially health), and purely intellectual—a necessary component has been the wide availability of scientific information, ranging from minimally processed data to cutting-edge research articles in newly developing fields. This information has been assembled as a matter of public responsibility by the individuals and institutions of the scientific community, largely with the support of public funding. [Ref. 35]

This sharing and dissemination of scientific data has led to incredible growth of the biotechnology industry over the past 10-20 years. This spread of scientific knowledge and technical equipment across the globe has taken root in private, educational and military programs. Scientists have expressed concern for the potential misuse of biotechnology but continue to train students (national and foreign) in the most sophisticated biotechnical methods. The danger inherent in this diffusion of biotechnological knowledge is illustrated in the concern over former Soviet Union bio-weaponeers that could potentially sell their services to nations seeking to implement a biological warfare program. [Ref. 36]

In this chapter I have attempted to illustrate the forces that have shaped the current information management structure of the HGP. In so doing I have highlighted that of the three information sharing paradigms the security paradigm is the least influential in the development of a scientific information exchange apparatus. This inattention to the guardedness of biologically sensitive information is not a failing of U.S. security professionals but is a result of the narrowly focused goals of the HGP and the scientists engaged in scientific research towards its goal. The task set forth by the HGP is vast, yet the organization of the project has allowed for a rapid build up of technologies to assist scientist in deciphering the human genome. With the successes of their

accomplishments coming to fruition, should the administrators and scientists of the project be the governor's of the technology that they are unleashing?

IV. SENSITIVITY ANALYSIS

A. FOR THE GOOD OF ALL MANKIND

The results of the Human Genome Project will revolutionize treatment of human illnesses by facilitating development of new medical products and processes. The following excerpt gives a good understanding of just how revolutionary medical products and processes will become:

> Analysis of the draft human genomic sequence has already led to the identification of genes for cystic fibrosis, breast cancer, hereditary deafness, hereditary skeletal disorders, and a form of diabetes--just to name a few. The draft sequence has also been used to identify an enormous number of single base variations in the genetic code that play a significant role in the disease process. These discoveries, as well as future discoveries, will have a profound impact on the future conduct of biomedical research. The translation of basic science advances into the clinical arena promises to revolutionize the practice of medicine. In the coming years, clinicians will be able to help their patients in ways they never thought possible. Physicians will be able to rapidly diagnose existing genetic diseases; pre-determine genetic risk for developing a disease; design novel therapeutic agents for the treatment and prevention of disease, rather than the treatment of the underlying symptoms; and prescribe a medical intervention based on a person's genetic information, reducing the chance of an allergic, or otherwise detrimental, drug reaction. [Ref. 37]

Biotechnology has pushed the boundaries of our understanding of nature and human biology. Future benefits from research due to the HGP will be in the fields of molecular medicine, microbial genomics, risk assessment, bioarchaeology, anthropology, evolution, and human migration, DNA forensics (identification), agriculture, livestock breeding, and bioprocessing [Ref. 38]. The most significant of these areas of interest concerning this thesis are molecular medicine, microbial genomics and risk assessment.

1. Molecular Medicine

Improvements in molecular medicine will assist medical professionals to diagnosis disease, detect genetic predispositions to disease earlier, improve drug design, improve gene therapy, and start the field of pharmacogenomics ("custom drugs"). This field will enable medical professionals to better treat the causes of human illness.

2. Microbial Genomics

Improvements in microbial genomics will assist scientists in myriad ways, such as bioremediation, potential energy sources and understanding disease vulnerability. This field will allow scientist to better understand the world of microorganisms and use that understanding to produce benefits for society. For this thesis the main benefit evolving from this field is the protection against biological agents.

3. Risk Assessment

Improvements in understanding the human genome will lead to risk assessment measures that will allow for early identification of genetic disease. In addition, the understanding of genomics will give scientists insight into how disease functions within the human genome.

B. RESULTS OF A DECADE

Developments of sequencing technology and techniques have made a significant impact on the cost and speed of developing a complete map of the human genome[20]. With the rapid development of sequencing technology, the HGP was able to readjust its target date of 2005 to 2003. This technological triumph is due to the scientific sharing of information, which led to an economic model of competition and innovation. The great promise of the HGP era[21] will be a result of the implementation of two of the three

[20] The cost of sequencing a single DNA base was about $10 then (1990); today, sequencing costs have fallen about 100-fold to $.10 to $.20 a base and still are dropping rapidly. See [http://www.ornl.gov/hgmis/project/privatesector.html]

[21] Functional Genomics study of the function of genes. Structural genomics study of 3D structure of proteins in order to describe function. Proteomics study of protein expression.

paradigms I have proposed (science and business). The third, (the security paradigm) could have an effect in the chronology of scientific developments in the HGP era.

The scientific information-sharing paradigm has led to the development of powerful tools to "spread the word" of Human Genome Project's research efforts on the internet. These tools are designed for people with no familiarity of the scientific processes involved in genomic research and genomics researchers alike. Tutorials assist in understanding technologies and the science behind genomic research[22]. In addition, search engines that assist in touring the draft sequence of the human genome contain significant information pertaining to genes of interest. Sites such as the Human Genome Project Information website[23] contain an extensive amount of information about the status of human genome research and tools available for public use to understand and use the information available, free of charge. This information distribution system is truly remarkable in the amount of scientific data and information pertaining to the human condition.

Sites that lead you directly to The Institute for Genomics Research[24] (TIGR) and the National Center for Biotechnology Information[25] (NCBI) contain powerful software tools that allow anyone to browse the human genome as it has been sequenced to-date[26]. GenBank is the NIH's sequence database maintained by the NCBI that stores the sequence data generated by the centers involved in the HGP. GenBank is one of three databases that make up the International Nucleotide Sequence Database collaboration[27]. All three institutions work together to make the sequence data generated by the Human Genome Project rapidly and freely accessible to scientific communities worldwide. [Ref. 39] In addition to supporting scientific communities these databases serve biotechnology

[22] Human Genome News, To Know Ourselves, DOE Primer on Molecular Genetics, and others See [http://www.ornl.gov/TechResources/Human_Genome/home.html]
[23] See [http://www.ornl.gov/TechResources/Human_Genome/home.html]
[24] See [http://www.tigr.org/tdb/]
[25] See [http://www.ncbi.nlm.nih.gov/]
[26] TIGR nonprofit research center setup by Craig Venter and Wallace Steinberg for the purpose of supplying sister companies with marketable DNA sequenced data to biotech companies. NCBI is a subdivision of the NIH and is a resource for molecular biology information, NCBI creates public databases, conducts research in computational biology, develops software tools for analyzing genome data, and disseminates biomedical information

corporations as well. The success of Celera Genomics[28] is due in part to the openness of public genome information. In addition to groundbreaking technological advances in sequencing technology and procedures[29], Celera Genomics was able to incorporate publicly funded genomic data into their operations but was able to selectively restrict information it deemed proprietary out of the company's genomic database.

The business paradigm has given an impetus for the development of private industry in the field of genomics and biotechnology. The affects of gene patenting have had a profound impact on private interest in developing significant products from genomic information. The beginnings of this genomic marketplace were a key factor in developing the sequencing technologies required by the HGP to accomplish the mission of completing the sequence of the human genome by 2005. Gene patenting has allowed private industry to begin to take over some of the cost associated with research and development. Genetic sequencers such as the ABI PRISM 3700, MegaBACE 1000, SCE 9600 and the CEQ 2000 have been instrumental in reducing the cost associated with DNA sequencing--a critical hurdle from the very beginning of the HGP. In addition, the high throughput of this new generation of sequencing technology has spurred business into developing software and databases capable of storing, manipulating and disseminating the raw data produced by the HGP. Genome informatics is playing a larger role in the biotechnology industry. Genome informatics tools such as BLAST, PHRED and PHRAP[30] are instrumental in continuing the scientific information paradigm to a higher level of collaboration.

The security paradigm is not well thought of among scientists in general. After all, international collaboration enhances scientists' capacity to better understand the natural world and thus strengthens the science base that is a source of important benefits to society [Ref. 40]. Restricting flows of information would result in inefficiency among

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[27] NCBI's partners in this effort include the European Bioinformatics Institute in the United Kingdom and the National Institute of Genetics in Japan. In addition, the Genome Database in the United States and the the European Molecular Biology Organization contribute to this genetic database management scheme.
[28] A leading corporation in genomics founded by ex-NIH scientist Craig Venter.
[29] Celera was the first genomics laboratory to receive ABI PRISM 3700 automated DNA sequencers developed by PE Applied Biosystems, a sister corporation to Celera Genomics. In addition, Celera Genomics President, Craig Venter, was responsible for the latest sequencing procedure, the shotgun procedure.

scientific programs that would ultimately stifle innovation and bog down industry. This would be a major blow to many spin-off projects of the HGP. The HGP has managed to generate a decentralized pool of knowledge that has spawned projects reliant on the current information-sharing apparatus. The ethical, legal and societal implications and potential for the misuse of biotechnology in the international community, coupled with the rapid expansion of scientific knowledge in these fields require an examination of risk involved in proceeding with current information management practices.

Biotechnology corporations have a different view of the security paradigm. Corporations must incorporate some element of guardedness in order to maintain a foothold in their industry. Without a security strategy, corporations would stand to lose millions of dollars in research and development if a competitor beat them to or produced a better product based on the same information. Once again, gene patenting plays a major role in creating a framework by which business can practice guardedness towards information for the benefit of producing goods.

C. THE RIGHT THING TO DO

Genomic research is a powerful tool. The process of studying a genome can be full of discoveries and surprises. Take the case presented in *Germs* of an Australian lab that discovered the effects of introducing the gene responsible for interluekin-4 production. In attempting to make mice infertile as a part of a pest-control project scientists used gene therapy to insert a mouse gene for regulating interleukin-4 that ultimately proved deadly for the mice in the experiment. The vector chosen was mousepox, a cousin of smallpox, and the addition of the regulatory gene produced immunity to vaccinated mice. This shocking result was attributed to the interluekin-4 (an immunity enhancer) gene shutting down the cellular arm of the mice immune system, rendering them unable to fight mousepox[31]. Of course this revelation was a concern for biological warfare professionals, due to the relation of mousepox to smallpox, this technique (publicly published) could circumvent the smallpox vaccine. [Ref. 41] This

[30] Computer algorithms that have become standard tools for analyzing DNA sequence data.
[31] "The Bugs of War," Nature, 411, 17 May 2001, p. 235

example of the potential of genomic research is a taste of what discoveries lay ahead of us, both intentional and unintentional.

The rapid expansion of biotechnological techniques and knowledge are outstripping society's ability to adjust to the new revelations. This rapid expansion will continue to hamper society's ability to provide the necessary guidance scientists require, in a timely manner. The Department of Energy has realized the impact of information inherent in the results of the HGP:

> While human genome research itself does not pose any new ethical dilemmas, the use of data arising from these studies presents challenges that need to be addressed before the data accumulate significantly. To assist in policy development, the ethics component of the HGP is funding conferences and research projects to identify and consider relevant issues, as well as activities to promote public awareness of these topics. [Ref. 42]

DOE and NIH have devoted 3% to 5% of their annual HGP budgets to studies of the project's ethical, legal, and social implications[32]. The Joint DOE-NIH ELSI program covers four program areas: (1) privacy and fair use of genetic information; (2) clinical integration of genetic technologies; (3) ethical issues surrounding genetic research; and (4) education and resources. DOE narrowed its ELSI scope to concentrate on genetic education, the privacy and fair use of personal genetic information, and genetics and the workplace. DOE supports peer-reviewed studies on the uses, effects, and implications of personal genetic information in various settings; its ownership, access, and protection in computerized databases and tissue and sample archives; and commercialized products of genome research. NHGRI's ELSI program also has been focused primarily on funding research and education projects, but was expanded and enhanced in the mid-1990s with the creation of two complementary entities: the Office of Policy and Public Affairs and an Intramural Office of Bioethics and Special Populations Research [Ref. 43]. DOE's goal is to democratize Human Genome Project information and make sure it is distributed widely. [Ref. 44]

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[32] See [http://www.ornl.gov/hgmis/resource/elsiprog.html].

Despite the overall strength of the ELSI research programs and their grant portfolios, there are some weaknesses. Specific content gaps exist in each of the portfolio's four program areas and there are a number of emerging issues–such as behavioral genetics, genetic enhancement techniques, and other emerging technologies (such as fetal cell sorting, pre-implantation genetic diagnosis, and the ability to test for adult onset disorders in children or even in the prenatal period)–that will require additional attention in the coming years. [Ref. 45] Regarding the Joint DOE-NHGRI self-proclaimed deficiencies in ELSI, fields of study such as vaccines, microbial research gene therapy and immunology pose significant concerns for elected policy makers with regards to duality. These fields pose questions relating to genetic enhancement techniques and emerging technologies mentioned previously.

1. Vaccines

In general, vaccines are wonderful. They have made a huge change in the world over the past two hundred years. They are perfect for protecting against many infectious diseases. What is different with biological weapons is that they can be based on a huge number of different biological agents (approximately 70 different types). Vaccinating somebody against 70 different infectious agents is virtually impossible from the health standpoint, the financial standpoint, and the scientific standpoint. [Ref. 46]

2. Microbial Research

The debate on whether to post microbial sequences on the internet or cloak them in secrecy has smoldered behind the scenes for years. "It's a question that still comes up," … raised by Department of Defense (DOD) scientists who worry that the information will find its way into the wrong hands. [Ref. 47] Proponents of the ongoing microbial genomic sequencing project back unfettered research and scientific openness, asserting that the same advances that may put more people at risk of germ warfare attacks also promise to accelerate critical research into the detection, prevention and treatment of germ-warfare agents. [Ref. 48]

3. Gene Therapy

Gene therapy is perhaps the most promising technique for curing genetic disorders in the future. The ability to permanently alter the genetic make-up of an individual (somatic cell gene therapy[33]) or to alter germ line cells (germ line gene therapy[34]) poses significant hope in combating and potentially terminating undesirable genetic mutations for individuals or future generations respectively. This ability could also be used to replace DNA in favor of a malignant gene. Much of gene therapy research is focused on utilizing "mother nature's" machinery: Viruses. The use of viruses to introduce DNA into an individual is very effective, viral vectors have evolved for this specific purpose for centuries. While this technology is still in its infancy the potential for its use as a cure or disease should be a great interest to public debate.

4. Immunology

Advances in our understanding of the human immune system will play a vital role in developing counter-measures against diseases (naturally occurring or man-made). In addition, the knowledge accumulated could lead to incidents, such as the mousepox example previously, that could lead to potentially dangerous organisms.

D. THE INFORMATION PERSPECTIVE

The bottom-line is that the HGP is big business as well as big science. The deluge of data and related technologies generated by the HGP and other genomic research presents a broad array of commercial opportunities. Seemingly limitless applications cross boundaries from medicine and food to energy and environmental resources, and predictions are that life sciences may become the largest sector in the U.S. economy. [Ref. 49] Any attempt to stifle the availability of information would meet fierce resistance from scientists and business. This big business environment was enabled by the rapid expansion of government investment through the HGP (see Figure

[33] Somatic cell gene therapy seeks to alter the genes of cells in an individual, this would repair damage in the individual alone.

[34] Germ line gene therapy seeks to alter the genes of the sex cells in an individual, this would allow for the avoidance of genetic defects in future generations.

1). This investment has in turn produced dividends through improvements to the HGP in areas critical to the continuation of research. No other area has been impacted more than sequencing technologies (See Figure 2)[35].

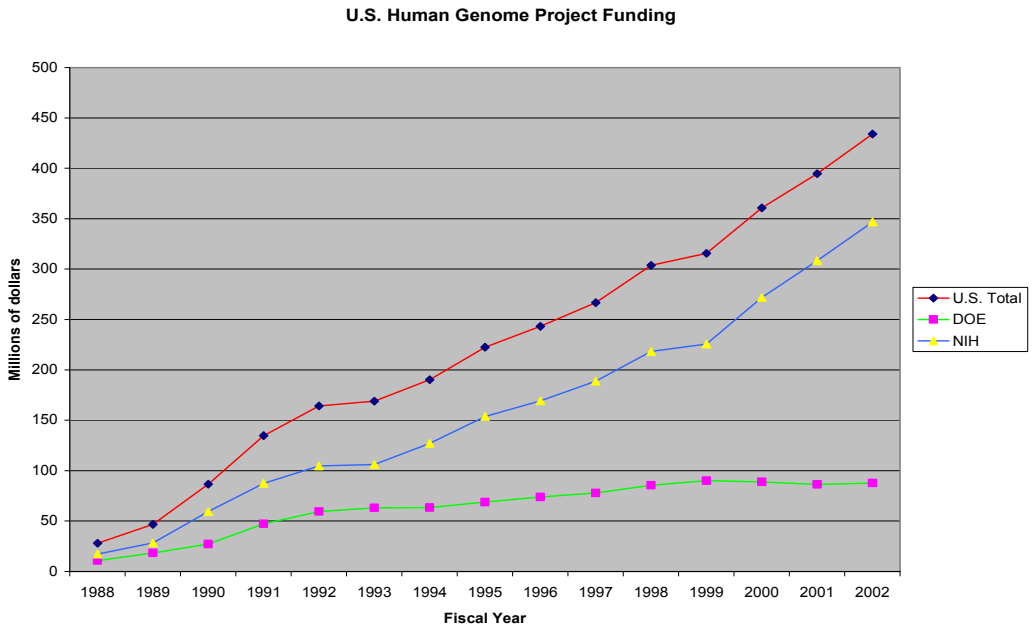

Figure 1. Funding for the U.S. Human Genome Project. From Ref. [50]

[35] Base pairs are two nitrogenous bases (Adenine and thymine or guanine and cytosine) held together by weak bonds, these bases make-up the double helix of a DNA that we call a chromosome. A sequence is the order of base pairs in a DNA molecule. See Department of Energy: Human Genome Project, Primer for Molecular Genetics (Washington, D.C.: U.S. Government Printing Office, June 1992).

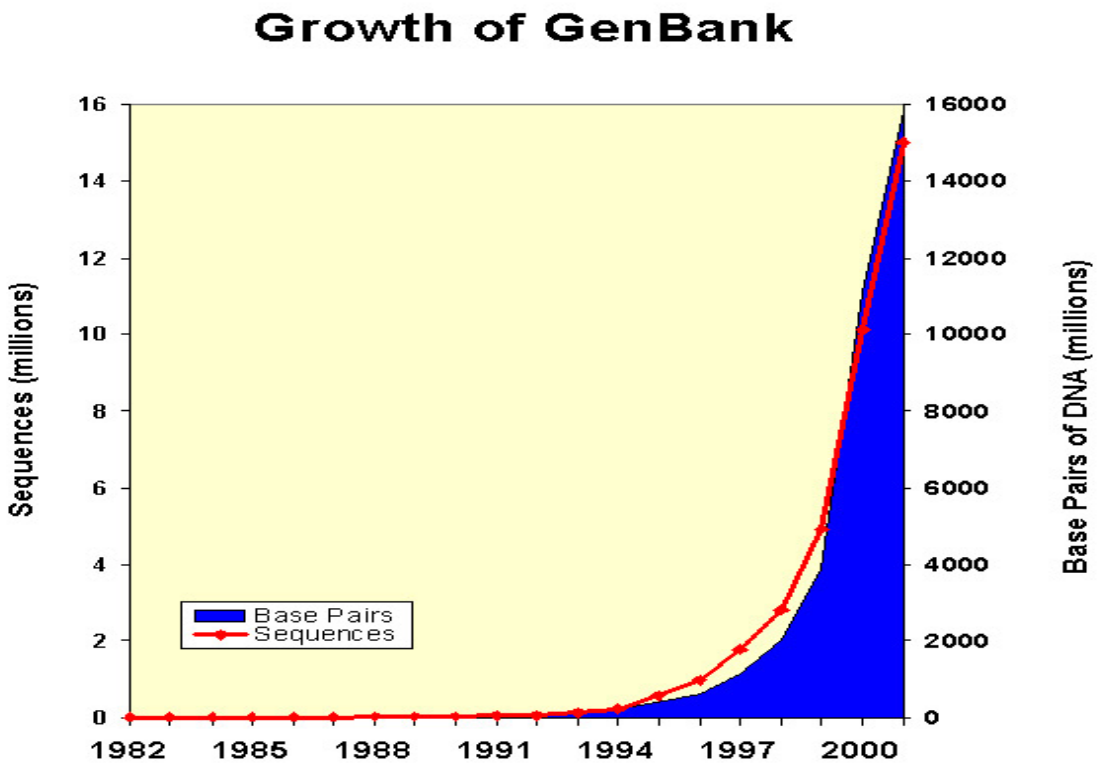

Figure 2. Growth of GenBank (1982-2000). From Ref. [51]

The biological revolution has been largely a success due to the sharing of scientific information for the purpose of exploiting that information to produce products in a free market economic model for the benefit of society. The HGP is at the center of this biological revolution. The HGP is by no means the root cause of this revolution but it has been a critical catalyst in the development of technologies that have advanced our understanding of basic biological processes. Once these processes are unleashed into our society they cannot be retracted. Herein lies the danger of the biological revolution. The dual-use nature of biotechnology is a concern that must be addressed in order to ensure security of mind and body in the international community.

> The features that make these technologies different—and that make their effects orders of magnitude greater than those of other technologies that have emerged in the past 50 years (with the possible exception of nuclear weapons)—also make the effects of their abuse potentially greater than those of other technologies. Yet, the level of control that is in the hands of the individual makes social governance much more complex than for

> technologies that require collective action to build, use, or maintain. The problem that emerges is no longer to ensure democratic control over a large and complex centralized system but rather to determine how much governance is necessary for a decentralized, distributed system and how society can accomplish this goal. [Ref. 52]

Advances in biotechnology have created gaping holes in the existing regime for the regulation of human biomedicine, which legislature and administrative agencies around the world have been racing to fill [Ref. 53]. The paces by which discoveries and innovation are developing are a great concern for the diffusion of biotechnological expertise throughout the world. The spread of recombinant knowledge through scientific exchanges and commerce has given even modestly skilled scientists the means to create havoc [Ref. 54]. Yet, the benefits of full and open access to scientific data in the information age are a force to be reckoned with. So we come full circle in trying to answer the question: what is the effect of government information management policies on the release of information regarding developing technologies via open source channels? And, what effect has government information management policy towards cooperation with private industry and the international consortium had on the spread of dual use technologies?

Perhaps the best solution to the questions posed by this thesis is expressed in the following statement:

> Based on its deliberations and understanding of the issues involved, the committee[36] believes that the following overarching principle should guide all policy decisions concerning the management and international exchange of scientific data in the natural sciences: The value of data lies in their use. Full and open access to scientific data should be adopted as the international norm for the exchange of scientific data derived from publicly funded research. The public-good interests[37] in the full and open

[36] "committee" refers to Committee on Issues of Transborder Flow of Scientific Data, U.S. National Committee for CODATA, Commission on Physical Sciences, Mathematics, and Applications, National Research Council.

[37] A class of economic good that refers to a product or service possessed of certain properties that lead to collective consumption or production, rather than private consumption or production. A public good is characterized by two attributes, nondepletability and nonexcludability (nonappropriability). See Bits of Power in List of References (p. 112)

> access to and use of scientific data need to be balanced against legitimate concerns for the protection of national security, individual privacy, and intellectual property. [Ref. 55]

The Human Genome Project is a program that requires an international exchange of scientific information. In this capacity the HGP is a tool for proliferation of a technology with a potential for mass destruction (or mass disruption). Currently, there are no intellectual, political, or proprietary barriers limiting international access to and use of these data. The barriers are technical and economic. The most important technical barrier involves equipment and infrastructure limitations on potential end users' capability to access and then make use of the wealth of information available. [Ref. 56]

In the next chapter I will explore trends in policy to deal with the duality problem inherent in biotechnology.

V. POLICY IMPLICATIONS

A. CURRENT TRENDS

The following excerpt from the book *Bits of Power* can best describe the current trend in information sharing paradigms concerning the Human Genome Project:

> Basic scientific research fuels most of our nation—and the world's—progress in science. Society uses the fruits of such research to expand the world's base of knowledge and applies that knowledge in myriad ways to create new wealth and to enhance the public welfare. Few people understand how scientific advances have made possible the ongoing improvements that are basic to the daily lives of everyone. Fewer still are aware of what it takes to achieve advances in science, or know that the scientific enterprise is becoming increasingly international in character. Freedom of inquiry, the full and open availability of scientific data on an international basis, and the open publication of results are cornerstones of basic research that U.S. law and tradition have long upheld. For many decades, the United States has been a leader in the collection and dissemination of scientific data, and in the discovery and creation of new knowledge. By sharing and exchanging data with the international community and by openly publishing the results of research, all countries, including the United States, have benefited. In this century's dramatic growth of scientific knowledge—an expansion motivated by a combination of forces including military, commercial, public benefit, and purely intellectual—a necessary component has been the wide availability of scientific information, ranging from minimally processed data to cutting-edge research articles in newly developing fields. This information has been assembled as a matter of public responsibility by the individuals and institutions of the scientific community, largely with the support of public funding. [Ref. 57]

The U.S. has taken the lead in publicly funding genomic research (see Figure 3). Appendix A displays a country and organizational funding chart of the overall international HGP effort from 1998 to 2000. The efforts of the U.S. to produce scientific data for open and free dissemination, coupled with the financial effort has led to an explosion of genomic data made possible by the HGP, and the revolution in information technology. Many scientists are having difficulty assimilating scientific data into

information that is useful in their research[38]. The creation of new fields of science such as bioinformatics is an adaptation that the HGP has developed to assist in its goal of collecting and disseminating scientific data and information.

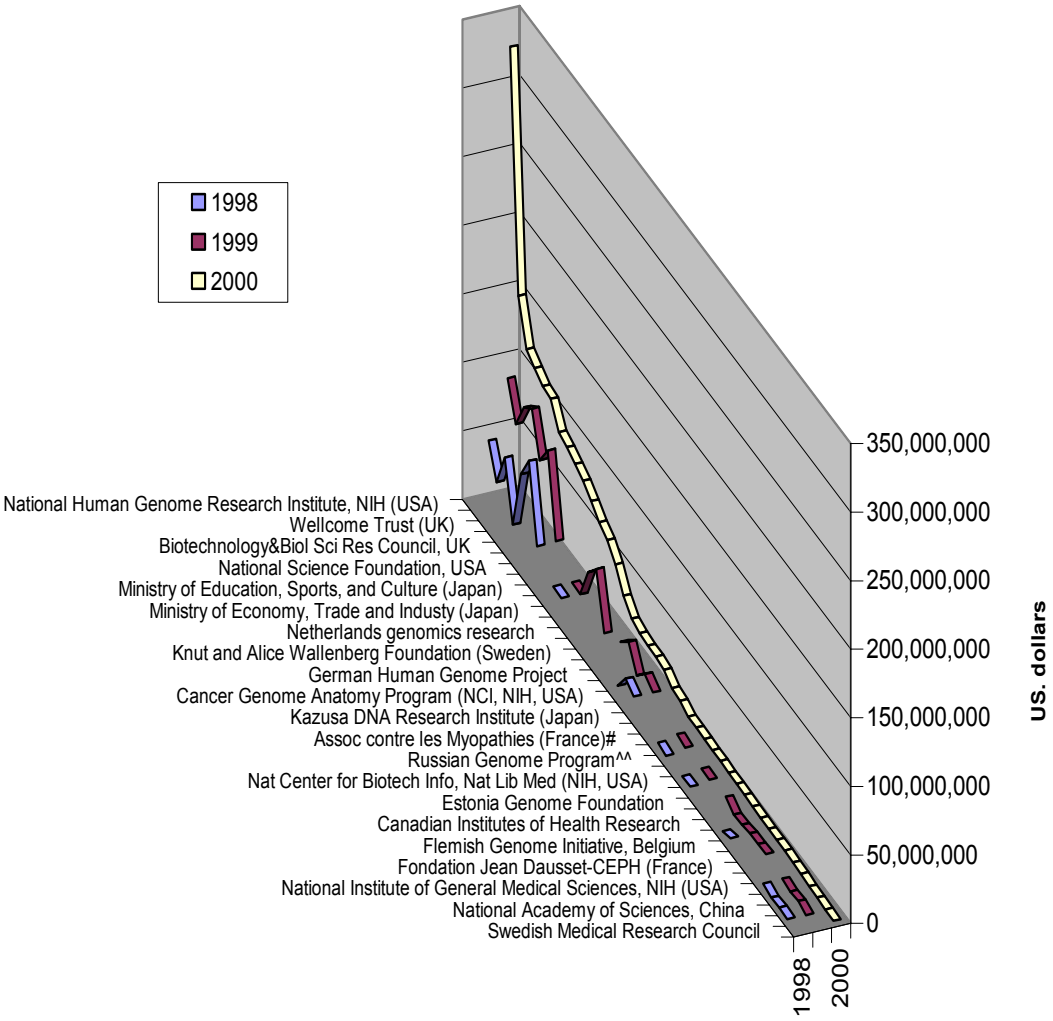

Figure 3. Funding for the Human Genome Project (1998-2000). From Ref. [61]

Concerns over the rapid expansion and dissemination of information and knowledge about genomics research, and biotechnology in general, have led many security professionals to raise public awareness on the issue of regulation. This call for

[38] Data are being generated so rapidly that the database doubles in size every 12 months. See Bit of Power in list of references p. 212

public awareness has been drowned out by the sensationalization of the potential benefits for medical treatments projected by the HGP and other genomics research. Until recently, the absence of a biological threat was been a significant factor in suppressing security concerns over biological warfare and biotechnology. This has not deterred scientists, such as Ken Alibek, from contemplating the future of biological warfare and the challenges and rewards posed by the dual-nature of biotechnology:

> In the 20th century, countries interested in biological weapons mostly developed them as weapons of mass destruction, a means to conduct wars. In the 21st century, we will see a significant shift. Everything is going to be done covertly. In some cases, biological weapons will be used in so-called "low intensity" military conflicts, or they will be used [for terrorism], brought to the US and used to infect people in the subway, for example.…..Russia still retains a huge, sophisticated biological weapons capability and expertise. This is the actual threat: not from the government, but from Russians with the knowledge. Some of them want to sell their expertise and knowledge-there are many buyers. The major concern is that in the event of a bioterrorist attack with well-trained people who know how to deploy biological weapons, the number of casualties would be unbelievably huge. Depending on the type of agents, deployment techniques, concentration of the agent, from dozens to hundreds of thousands. We need to take a very aggressive approach and start developing real protection against biological weapons. We need a special government board overseeing this work, which covers everything from detection, identification, protective garments and disinfection, to the organisational tactics of medical services, diagnostics issues, treatment, re-treatment, and urgent prophylaxis. [Ref. 58]

The current threat of biological warfare is real. We have all seen the danger involved in a biological attack in the recent anthrax attacks in the U.S. Since the U.S. dismantled its offensive biological program in 1969, the emphasis on a defensive program and a non-proliferation regime has been our main defense against the threat of biological agents. The history of the absorption of technology into the operational and warfighting capabilities of the Department of Defense suggests a reason for our vulnerability to biological warfare. World War I was a conflict that forced chemists and warfighters to talk with one another; World War II as a conflict that brought physicists

and warfighters together; the Cold War as a history of Pentagon investments in computers, electronics, and telecommunication skills. But, this framework does not include events that led to the development and integration of biologists with the Pentagon. [Ref. 59] I would also point out that the incorporation of doctors and scientists in our non-proliferation efforts is also a failing that we must address[39]. "The common interests of all scientists, of science, and indeed of society in general are best served by as full and open an exchange of scientific information as possible, consistent with the preservation of scientists' capacity to continue their investigations….Because the scientific community is not the only sector with an interest in the handling of scientific data and information, scientists need to remain involved in the current policy debate that will affect the prospects for continuing open, global access to scientific data." [Ref. 60]

As a response to the September 11 and anthrax attacks in the U.S., the President is taking steps that will significantly improve our ability to protect citizens against the threat of bioterrorism. The President has proposed a 319 percent budget increase in FY 2003 towards a defense against biological terrorism, an increase of $4.5 billion. This new funding will focus on: strengthening the state and local health systems, including by enhancing medical communications and disease surveillance capabilities, to maximize their contribution to the overall biodefense of the nation; improving specialized federal capabilities to respond in coordination with state and local governments, and private capabilities in the event of a bioterrorist incident and build up the National Pharmaceutical Stockpile; meeting the medical needs of our bioterrorism response plans by developing specific new vaccines, medicines, and diagnostic tests through an aggressive research and development program. [Ref. 62]

B. POTENTIAL FOR CONTROLS

The impetus for monitoring dual-use biotechnology equipment, information and knowledge can be illustrated in a November 1, 2001 statement by President George W. Bush:

[39] British Medical Association, Biotechnology, Weapons and Humanity, Hardwood Academic, 1999, p. 100.

> Disease has long been the deadliest enemy of mankind. Infectious diseases make no distinctions among people and recognize no borders. We have fought the causes and consequences of disease throughout history and must continue to do so with every available means. All civilized nations reject as intolerable the use of disease and biological weapons as instruments of war and terror. [Ref. 63]

To-date most efforts to control biological weapons and biotechnology have produced a stream of international agreements and cooperative coalitions. International attempts to stem biological warfare proliferation have focused either on suppliers or on self-disclosures and declarations. The proliferation attempts by suppliers are conducted through the Australia Group. The self-disclosure and declarations are conducted through the Biological and Toxin Weapons Convention (BWC). Both the Australia Group and the BWC have drawbacks. The dual-use nature of equipment makes it difficult for suppliers to establish what equipment requires tracking and what does not. The self-disclosure and declaration protocol can be circumvented by claiming legitimate defensive research in biological agents. [Ref. 64]

Participants in the Australia Group do not undertake any legally binding obligations: the effectiveness of the cooperation between participants depends solely on their commitment to CBW non-proliferation goals and the effectiveness of the measures they each take on a national basis. The participants in the Australia Group encourage all countries to take the necessary steps to ensure that they and their industries are not contributing to the spread of biological and chemical weapons. Export licensing measures demonstrate the determination of AG countries to avoid involvement in the proliferation of these weapons in violation of international law and norms. [Ref. 65]

Earlier this year, the U.S. rejected a protocol to the treaty that all other countries had agreed to, which would have made members exchange information and submit to inspections aimed at bolstering the ban on biological weapons. Pharmaceutical and biotechnology companies objected to provisions that would allow random inspections of their facilities, fearing that commercial secrets would be compromised. Proponents of stringent arms control were not satisfied with the time lag given to potential inspection

sites. Any facility receiving a random visit would be given two weeks notice, so those involved in biowarfare could easily disguise their activities. Even 'challenge' inspections, made following specific allegations that the convention had been breached, would allow a lag of 108 hours. [Ref. 66]

Bolstering the BWC is critical because unlike other treaties it has no secretariat, no existence in the real world, apart from meetings of members. The U.S. has asked countries instead, to call for inspections of suspicious disease outbreaks by the U.N. It is also pushing for laws making possession of bioweapons illegal, and controls on biotechnology and pathogens. But it opposes any continuation of talks among treaty members aimed at setting up anything like the rejected protocol[40]. Third World countries, especially Iran and China, insist such talks must continue. The European Union is trying to bridge the gap with a proposal that treaty members at least keep meeting annually to discuss common concerns, starting before next April. The E.U. also wants members to set up working groups of scientific experts to monitor developments in biotechnology which could pose new threats, or new means of tracing or treating germ weapons. [Ref. 67] The meeting ended with governments pledging to meet again next November, but making no other final declaration.

These two non-proliferation agreements are the cornerstones of U.S. efforts to cease the proliferation of technologies related to the production of biological weapons. Other efforts to reduce this threat include the Russia-U.S.-U.K. trilateral agreement, signed in September 1992 that focuses on confidence building measures that promote transparency of each nation's biological warfare capabilities. In fact, confidence-building measures are a barrier that the BWC has been attempting to address since its inception[41]. The 1925 Geneva Protocol, ratified by U.S. April 10, 1975, prohibits the use in war of

[40]The US introduced a demand to abolish a mandate under which treaty members have been negotiating legally-binding compliance measures. See [http://www.newscientist.com/hottopics/bioterrorism/bioterrorism.jsp?id=ns99991667]

[41] In accordance with Article XII of the BTWC, Review Conferences have been held at approximately five-year intervals since it entered into force in 1975. At the Second Review Conference of the BTWC in 1986, the States Parties agreed some measures intended to strengthen compliance with the Convention and to improve transparency. These were enhanced and extended at the Third Review Conference in 1991. These confidence-building measures (CBMs) consist of annual exchanges of data and information, as well as declarations of past and present activities of relevance to the Convention. See [http://www.brad.ac.uk/acad/sbtwc/btwc/cbms.html]

asphyxiating, poisonous or other gases, and of all analogous liquids, materials or devices, and bacteriological methods. Generally accepted as international law the Geneva Protocol does not apply to nations under attack by non-signatory states.

C. INFORMATION STRATEGY

A statement by former Secretary of State Madeline Albright gives perspective on how the U.S. government sees its role in the international community with regards to scientific knowledge. "In a world being transformed by technology, good science is vital to good diplomacy...Whether the issue is countering weapons of mass destruction, dealing with infectious diseases, or expanding the global economy while protecting the global environment, if we are to get our international strategies right we must get our science right." [Ref. 68] This coupling of science with diplomacy is an important realization to understanding what is at stake with regard to the proliferation of biotechnology.

In their book, *The Emergence of Nooplotitik: Toward an American Information Strategy Noopolitik*, John Arquilla and David Ronfeldt argue for "an articulated, integrated, U.S. information strategy" focused upon American national security [Ref. 69].

> Strategy, at its best, knits together ends and means, no matter how various and disparate, into a cohesive pattern. In the case of an American information strategy, this requires balancing the need to guard and secure access to many informational capabilities and resources, with the opportunity to achieve national aims by fostering as much openness as practicable in the international system. Of course, an American strategy that supports a substantial amount of openness is sure to base itself on the assumption that greater interconnectivity leads to more liberal political development—an updated version of Lipset's (1960) "optimistic equation," which saw democracy moving in tandem with prosperity. Even so, it may be prudent to hedge against atavistic tendencies (e.g., information age totalitarianism) by means of continuing guardedness. Our term to represent such a strategic balancing act is "guarded openness." [Ref. 70]

The concept posed by Arquilla and Ronfeldt is echoed by Dr. Dan Kuehl's *Information Power: A New Paradigm for National Security in the Interconnected Age*[42]. The concept of information as a component of power is increasingly relevant to the diffusion of biotechnology and the threat it poses to national security. As a leader in the dissemination of information it is incumbent on the U.S. to lead the international community in a regulation regime that addresses the information power inherent in biotechnology. The U.S. must strive to bring the BWC into a more useful tool for the non-proliferation of dangerous technologies in the international community. However, the U.S. must continue its national efforts to enhance medical communications and disease surveillance capabilities at the state and local community levels and impress this capability on the international community. This creation of an epidemiological tracking network is seen by many security and medical professionals[43] as being essential for identifying terrorist use of biological agents.

D. CONCLUSION

The challenge of biotechnology, where good and bad are intimately connected, presents a dilemma that must be dealt with. Regulation of biotechnological developments and institutional oversight that will discriminate between those technological advances that further human flourishing, and those that pose a threat of human dignity and well-being are needed to ensure the public utility of these technologies is a must. These regulatory institutions must have the power to enforce discrimination at a nation and, ultimately, an international level. [Ref. 71] In order to accomplishing this regulation Dr. Fukuyama states:

> In proscribing an approach for the regulation of biotechnology… a lot of positive benefits will come from the biotechnology revolution; this is why we should pursue a regulatory approach rather than seeking to ban specific

[42] Use of information content and technology as strategic instruments to shape fundamental political, economic, military, and cultural forces on a long-term basis to affect the global behavior of government, supra-governmental organizations, and societies to support national security. See [http://www.ndu.edu/irmc/].

[43] British Medical Association, Biotechnology Weapons and Humanity (Amsterdam: Hardwood Academic, 1999),

> technologies. But …"it is extremely important for the political community to lay down a marker that the people who determine the pace and scope of technological progress and development [are] not the scientific community, not the pharmaceutical industry, not the community of research scientists. It is the democratically constituted political community that is sovereign over these issues." Some people argue that globalization will make it impossible to control development in the field of biotechnology. But international regulatory regimes begin with national regulations…and the first step is to focus on the national institutions that should oversee advances in biotech. In some cases existing regulatory institutions, such as the Food and Drug Administration, may be able to deal with changing technologies, but in many other cases we will have to create new bodies that are prepared to take novel regulatory approaches. ….of the models currently in practice, formal regulation, not self-regulation, is the answer….in areas such as banking, those in industry can be left to agree upon standards among themselves, but the biotechnology industry will have no adequate incentives to regulate itself in ways that protect the public interest. [Ref. 72]

Throughout this thesis I have wrestled with the inherently dual-use nature of biotechnology and have tried to develop a means to frame the problem posed by the biotechnology in an information environment. By using the Human Genome Project as a case study, I have developed a framework by which regulation, or potential regulation, of biotechnology could be addressed. Understanding the potential of biotechnology is only half of the problem. Knowing how regulation will affect society and who should be involved in regulation (or even if regulation should be considered) is a question that should be addressed by the "consumers" of biotechnology products. In today's supercharged information technology environment biotechnology has become an international concern. Biological warfare is only one issue that I have chosen to address, but the ramifications of the coming biotechnology revolution have an impact across the globe.

Regulation is not the all-encompassing answer to the biotechnology threat. In fact, the current regulatory regime is known to be faulty. The former Soviet Union, Iraq, and potentially Iran are all known to have development of an offensive BW program

while having ratified the BWC[44]. Regulatory regimes apply strictly to those nations that submit to the terms of the agreement. The Australia Group consists of 34 countries. This small number poses a problem for tracking technologies coming out of countries that are not a part of the Australia Group. Appendix B is a listing of all nations currently involved in the Australia Group.

In spite of the difficulties experienced in tackling the proliferation of biotechnology in the international arena the U.S. must continue to develop an effective non-proliferation regime. In addition, the paradigm interactions posed in this thesis would point to a system of information sharing that would enable medical professionals to better cope with the potential use of biological agents. At a minimum steps must be taken to ensure that medical personnel have the best information available to detect, treat and prevent the spread (intentional or unintentional) of disease. Scientists involved in biotechnology, and genomics specifically, must take a lead in directing efforts to counter the biological threat posed by the diffusion of biotechnology.

[44] The Worldwide Biological Warfare Weapons Threat, (Washington, D.C.: Government Printing Office, 2001) 14.

APPENDIX A

Genomics Research Funding 1998-2000

In descending order of Year 2000 funding ($ US*)

	1998	1999	2000
Total	**721,013,151**	**1,141,497,345**	**1,805,325,883**
National Human Genome Research Institute, NIH (USA)	210,891,000	270,733,000	326,391,000
Genome Canada			152,542,373
Wellcome Trust (UK)	61,273,006	103,511,450	121,406,728
Science and Technology Agency (Japan)##	38,899,682	77,867,925	115,431,373
Biotechnology&Biol Sci Res Council, UK	64,417,178	97,709,924	110,091,743
European Commission	23,479,189	104,602,510	108,459,870
National Science Foundation, USA	68,000,000	75,000,000	92,000,000
US Department of Energy	85,500,000	89,800,000	88,900,000
Ministry of Education, Sports, and Culture (Japan)##	31,025,468	31,427,673	84,398,693
German microbial genomes&proteomics#			80,000,000
Ministry of Economy, Trade and Industy (Japan)^	17,354,305	17,081,761	72,908,497
Ministry of Health and Welfare (Japan)	16,474,026	16,094,340	65,359,477
Netherlands genomics research#		40,000,000	60,000,000
American Cancer Society (USA)		50,000,000	50,000,000
Knut and Alice Wallenberg Foundation (Sweden)	5,000,000	11,000,000	35,000,000
GenHomme Program, France#			26,000,000
German Human Genome Project	19,900,498	20,202,020	23,195,876
The SNP Consortium		28,000,000	22,000,000
Cancer Genome Anatomy Program (NCI, NIH, USA)**	7,000,000	11,300,000	21,800,000
Howard Hughes Medical Institute (USA)	20,000,000	20,000,000	20,000,000
Kazusa DNA Research Institute (Japan)	14,800,000	14,500,000	14,400,000
Imperial Cancer Research Fund (UK)			12,894,495
Assoc contre les Myopathies (France)#			9,200,000
Centre National de Sequencage Genoscope (France)	4,522,388	7,435,897	8,961,832
Russian Genome Program^^	2,783,100	5,382,471	8,286,800
Korea Research Institute of Bioscience~			8,000,000
Nat Center for Biotech Info, Nat Lib Med (NIH, USA)	3,500,000	5,800,000	8,000,000
Merck Genome Research Institute (USA)***	3,700,000	5,350,000	7,000,000
Estonia Genome Foundation			6,941,665
Ministry of Science and Technology, China^	3,623,188	8,454,106	6,642,512
Canadian Institutes of Health Research#$		3,331,794	5,925,620
National Natural Science Foundation, China^	2,415,459	3,623,188	5,434,783
Flemish Genome Initiative, Belgium	5,000,000	5,100,000	5,200,000
Environmental Genome Program (NIEHS, NIH, USA)		5,189,000	5,008,000
Fondation Jean Dausset-CEPH (France)	6,316,916	5,603,448	4,956,616
US Defense Advanced Research Projects Agency			4,000,000
National Institute of General Medical Sciences, NIH (USA)	3,000,000	3,200,000	3,500,000

Australian Genome Research Facility	610,687	1,615,385	2,213,740
National Academy of Sciences, China^	1,207,729	2,415,459	1,811,594
Program in Medical Genomics, NHMRC (Australia)	319,331	165,993	862,595
Swedish Medical Research Council			200,000

^*from Genome Canada 2000-2001 annual report
**Based on meeting with Robert Strausberg 7 September 2000. They include CGAP and the Genetic Annotation Initiative of NCI as well as some NIAID and other institutes' funds for the Mammalian Gene Collection.
***Currency conversions made using Purchasing Power Parity, per OECD figures Feb 2001 update (see http://www.oecd.org/std/ppp/pps.htm, and PPP data table at p. 7 of http://www.oecd.org//std/ppp1.pdf), except China (not an OECD member; used UNSTATS currency conversion factor (exchange rate) instead.
#Data contributed by Manuel Hallen, European Commission, using his currency conversions
##STA and MESC (Monbusho) unified in 2000 to become Ministry of Education, Sports, Culture, Science and Technology (MEXT; Monbokagusho), but genome program budgets are shown here carried over from original ministries
^Data contributed by Huanming Yang, Director of the Beijing Genomics Institute, 4 March 2001
#$Canadian Institute of Health Research figures from Veeran-Anne Singh, 26 October 2001
^^Data (in $US) contributed by Andrei Mirzabekov, Argonne National Laboraory (Illinois) and Englehardt Institute of Molecular Biology (Moscow) 17 May 2001
***Merck's 1999 report on corporate philanthropy specifies "genome research" at $3.7M for 1998. Figure for 2000 based on Mouse Genome Sequencing Consortium funding [$6.5M; http://www.mgri.org/grants.html#Consortium] and the Alliance for Cellular Signaling [$500,000; http://www.mgri.org/grants.html#Southwestern] so a slight underestimate, MGRI's two main grants; 1999 figure interpolated between 1998 and 2000 figures.
Government figures from Japan (STA, MESC/MEXT, MITI, and MHW) forwarded by David Cyranoski, April 2001
~Budget figures on Korea from Robert Triendl and Renee Yoon, "Growth of Genomics & Bioinformatics in Asia," *Genetic Engineering News* **21** (15): 5051, Sept 1, 2001.

APPENDIX B

Participating Members of the Australia Group

Argentina	Finland	Luxembourg	Switzerland
Australia	France	Netherlands	Republic of Turkey
Austria	Germany	New Zealand	United Kingdom
Belgium	Greece	Norway	United States
Bulgaria	Hungary	Poland	
Canada	Iceland	Portugal	
Czech Republic	Ireland	Romania	
Republic of Cyprus	Italy	Slovak Republic	
Denmark	Japan	Spain	
European Commission	Republic Of Korea	Sweden	

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